

CLA Registration Committee

December 18, 2018



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Tank Mix Label Language



Goals:

- Allow recommending tank mix products on the label by brand and use rate.
- List product use rate in lb AI on label one time only.
- Active ingredient and registration number of tank mix partner product listed on label, one time only.
- State tank mix disclaimer text on label, one time only.

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Miscellaneous Label Topics

- Number of applications: where there is a range of use rates for a single application, allow for multiple applications within the maximum use rate per year or per season.
- Reviewers have requested changes to text that is taken verbatim from the Label Review Manual or PR notices.
- PRD and RD may require label statements for the same product that conflict with each other.
- Registrants are uncertain how to handle California requirements for Prop 65 label language.

75-day data deficiency letters for labeling issues

- From the Pesticide Registration Manual (ch. 5): “At any time after the [screens], ... the Agency may determine that an application is incomplete ... deficiency letter may be issued ... the applicant has 75 days in which to address the deficiencies ...”
- If all required data are submitted according to the 21-day front end screen, why is a 75-day deficiency letter issued?
 - ✓ FIFRA section 33(f)(4)(B), “Initial Content and Preliminary Technical Screenings,” – 21-day front end screen and 45/90 technical screen.
- Labeling issues noted in 75-day deficiency letter go beyond section of label being amended.
- Data review frequently triggers additional label revisions.
- Concern about efficient use of resources if label must be reviewed both before and after data review.

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Mandated label mitigation on 24(c) Labels as part of Reg Review process

Must the registrant add label mitigation to current 24(c) labels when a chemical goes through registration review?

Registrant comments:

- Since the SLA issues the 24(c) registration, the SLA should communicate the mitigation required. If mitigation language pertains only to the specific use pattern covered by the 24(c), EPA should notify the SLA to require the mitigation on the 24(c) label.
- If the mitigation language applies to a more general group of use patterns, e.g., spray height restrictions or plant-back restrictions, then the mitigation language on the container label should be followed.
- 24(c) registrations always refer back to the full section 3 label, including mitigation.
- There could be conflicts between the 24(c) and container labels.
- Resource concerns for the SLAs if they require general mitigation on all previously granted 24(c) registrations.

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